

REMARKS

In the September 10, 2002 Office Action claims 1-21, 27, 53-55, 57, 58, 60-64, and 79-145, were rejected. In this response, claims 1 and 104 have been amended. Claims 1-21, 27, 53-55, 57, 58, 60-64, and 79-145, remain pending.

Applicants respectfully submit that no new matter has been added by the amendments to the claims.

Rejection Under 35 U.S.C. § 112

Claims 103 and 145 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action states:

The term "AUC₀₋₂₄" in claims 103 and 145 renders the claims indefinite. The term "AUC₀₋₂₄" is not defined in the specification and claim. Therefore, the scope of the claims is indefinite as to the identification/description.

Applicants respectfully traverse this rejection.

In rejecting a claim under 35 U.S.C. § 112, second paragraph, the Examiner must establish that one of ordinary skill in the pertinent art, when reading the claim in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the specific area set out and circumscribed by the claim. *Ex parte Wu*, 10 USPQ 2d 2031m 2033 (B.P.A.I. 1989).

The Examiner's attention is respectfully directed to page 33, Table 7, of the Specification as originally filed, where the definition of the term "AUC₀₋₂₄" is defined:

AUC₀₋₂₄ -- area under the curve from 0 to 24 hours, determined using the linear trapezoidal rule.

The Examiner's attention is also respectfully directed to page 39, line 5, where the dose proportionality for AndroGel® is determined using "AUC₀₋₂₄." Table 8(g) on page 49 of the specification provides the "AUC₀₋₂₄" calculations for days 30, 60, 90, and 180 after transdermal testosterone application.

Applicants maintain that the term "AUC₀₋₂₄" when read in light of the supporting specification clearly defines the metes and bounds of the invention and clearly sets forth the subject matter of the invention. Withdrawal of this rejection of claims 103 and 145 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Rejection Under 35 U.S.C. § 103

Claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 were rejected under 35 U.S.C. § 103(a) as being unpatentable under Allen (WO 96/227372, PTO-892) and Moreland *et al.* (PTO-892) and Mak *et al.* (WO 99/24041, PTO-892). The Examiner stated:

Applicants are suggested to amend the composition herein employed in the instant claimed methods, to be consistent with the composition in the parent application 09/651,777 which has been allowed, in order to place the instant application in condition for allowance.

Applicants respectfully traverse this rejection in light of the amended claims.

Reconsideration and withdrawal of this 35 U.S.C. § 103 rejection of claims 1-21, 27, 53-55, 57-58, 60-64, and 79-145 is respectfully requested.

CONCLUSION

With entry of the above Amendment and in view of the foregoing remarks, it is respectfully submitted that claims 1-21, 27, 53-55, 57, 58, 60-64, and 79-145 are in condition for allowance.

None of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

Submitted below is separate page titled "Version with Marking to Show Changes Made in the Claims," showing a marked-up copy of prior pending claims.

It is respectfully submitted in view of the foregoing Amendments and Remarks that all of the objections and rejections in the Office Action dated September 10, 2002 have been overcome and should be withdrawn. Applicants respectfully request early and favorable notification to that effect.

If, in the opinion of the Examiner, a phone call may help to expedite prosecution of this application, the Examiner is invited to call Applicant's undersigned attorney at (312) 701-8775.

Respectfully submitted,

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Version with Markings to Show Changes Made In the Claims

1. (Twice Amended) A method of treating hypogonadism in a male subject in need thereof, comprising administering a composition to a selected area of skin of the male subject in a pharmacologically effective amount to treat the hypogonadism, wherein the composition consists essentially of [comprises]:

- a) about 0.5 [0.1] % to about 10 % testosterone;
- b) about 30 % to about 98 % alcohol selected from the group consisting of ethanol, and isopropanol;
- c) about 0.1 % to about 5 % isopropyl myristate;
- d) about 1 % to about 5 % sodium hydroxide; and
- e) about 0.1 % to about 5 % gelling agent; and

wherein the percentages are weight to weight of the composition, and the testosterone is absorbed into bloodstream of the subject at a rate and duration that maintains a circulating serum concentration of the testosterone greater than about 400 ng testosterone per dl serum during a time period beginning about 2 hours after administration and ending about 24 hours after administration.

104. (Amended) A method of treating hypogonadism in a male subject in need thereof, comprising:

- (a) preparing a composition consisting essentially of: [which comprises]
 - 1) about 0.5 [0.1] % to about 10 % testosterone;
 - 2) about 30 % to about 98 % alcohol selected from the group consisting of ethanol, and isopropanol;
 - 3) about 0.1 % to about 5 % isopropyl myristate;

4) about 1 % to about 5 % sodium hydroxide; and

5) about 0.1 % to about 5 % gelling agent; and

(b) applying the composition to a selected area of skin of the male subject in an amount effective to treat the hypogonadism;

wherein the percentages are weight to weight of the composition.